



D-1137

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
McGrady, et al.)	
)	
Application No.: 09/849,625)	Art Unit 3627
)	
Confirmation No.: 9504)	
)	
Filed: May 4, 2001)	Patent Examiner
)	Oger Garcia Ade
)	
Title: Method of Tracking and)	
Dispensing Medical Items)	

Director of Technology Center 3600
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated January 19, 2007, kindly enter Applicants' Petition
in the above identified Application without prejudice as follows:

**PETITION FOR WITHDRAWAL OF
RESTRICTION REQUIREMENT PURSUANT TO 37 C.F.R. § 1.144**

Applicants respectfully petition for withdrawal of the restriction requirement presented in the Office Action ("Action") dated August 16, 2006. Reconsideration of the restriction requirement was requested pursuant to 37 C.F.R. § 1.143 on August 26, 2006. The restriction requirement was made final in the Office Action dated January 19, 2007.

The Prosecution History

The record shows that the following dates and papers are associated with this application:

1. 03/09/04 Non final rejection
2. 09/07/04 1st restriction requirement
3. 09/22/04 Request for reconsideration of the requirement
4. 12/08/04 2nd restriction requirement
5. 12/17/04 Request for reconsideration of the requirement
6. 03/25/05 3rd restriction requirement
7. 04/14/05 Request for reconsideration of the requirement
8. 06/28/05 Non final rejection
9. 08/10/05 Petition that the requirement be withdrawn
10. 03/07/06 Non final rejection
11. 08/16/06 4th restriction requirement
12. 08/26/06 Request for reconsideration of the requirement
13. 01/19/07 Restriction requirement made final

As evidenced by the prosecution history, the Office continues to improperly attempt to impose a restriction requirement. Applicants have shown (including their previous petition of 08/10/05) each attempt to be in clear error.

The Restriction Requirement is not legally proper because it is not timely

MPEP § 811 indicates that an examiner is to "make a proper requirement as early as possible in the prosecution, in the first action if possible." 37 C.F.R. § 1.142 indicates that the requirement is to "be made before any action on the merits." The Applicants respectfully submit that the 4th restriction requirement (dated 08/16/06) is not in compliance with statutes, rules, and Office procedures. This application has received numerous actions on the merit (e.g., the rejections dated 03/09/04, 06/28/05, and 03/07/06). The time for requiring restriction has expired. Thus, the requirement is not legally proper and should be withdrawn.

Furthermore, the Office's repetitive and unsupported allegations of a need for restriction appear to be an effort to deny Applicants judicial review of the refusal to grant their application. If true, this constitutes an abuse of agency authority. Such actions violate the Administrative Procedures Act, 5 U.S.C. § 701 *et seq.* Such agency action also violates the fundamental legal principle that an administrative agency may not avoid review of its actions by engaging in repetitive activity which does not remain in place long enough to enable judicial review. *Southern Pacific Terminal Co. v. Interstate Commerce Com.*, 219 U.S. 498, 55 L.Ed. 310, 31 S. Cr. 279 (1911).

The Restriction Requirement is not legally proper because there is no serious burden

MPEP § 803 sets forth criteria for a proper election requirement. One of the criteria is that there must be a serious burden on the Examiner in order for election to be required.

Conversely, if the search and examination of an entire application can be made without serious burden on an Examiner, then it must be examined on the merits (which has already occurred). As discussed in more detail hereinafter, as the application has already received numerous complete actions on the merits, the criteria for establishing serious burden has not been met.

The fact that numerous examinations on the merits have already occurred is *prima facie* evidence that there is no serious burden. Applicants respectfully submit that the requirement is not legally proper because the criteria for serious burden have not been met. Rather, the lengthy prosecution history evidence is in direct conflict with the latest allegation of serious burden. The application has *already* been searched, there have *already* been numerous examinations of the recited subject matter, and these examinations were on the merits. The claims corresponding to each of the alleged inventions were already fully examined. The prosecution record itself is clear evidence that there was (and continues to be) no serious burden. How can the current Examiner allege that the burden to examine the application is too hard when the prior Examiners have already easily performed a complete action on the merits?

Contrary to the current Examiner's opinion, (by inference) the prior Examiners (e.g., Steven McAllister and Bryan Jaketic) assigned to this application concluded that there was no need of restriction requirement. Hopefully, the Actions of these prior Examiners were "complete as to all matters" in accordance with 37 C.F.R. 1.104(b). Further, the standards of examination "must be the same throughout the Office" (MPEP § 706(I)). Thus, the prior Examiners' conclusion of no need for restriction requirement constitutes prosecution history estoppel. Otherwise, the Office is admitting on the record that all of the previous Office Actions by the prior Examiners did not meet the examination standard of the Office. Is the Office admitting that

it did not previously conduct a proper handling of this application (which necessitated needless Responses by Applicants thereto)? Also, all of the Office Actions have come from the same Art Unit. Is the Office admitting that the examination standard of that Art Unit freely changes?

The Office has no legal basis for restriction requirement just because an application was reassigned to yet another Examiner, especially in the same Art Unit, as is the current situation. Again, this would violate the Office's requirement for applying a same standard of examination. Applicants request that the application be returned to a previous Examiner (who disagrees with the current Examiner's assessment of serious burden, as evidence by the record).

The fact remains, the application was already fully acted upon, the recited subject matter was already fully examined, and the application has already received multiple complete actions on the merits. As the prosecution history shows, this application has received numerous Office Actions. An Art Unit is not authorized to use application reassignment as an excuse to circumvent the rules and Office procedures. Unless the Office has a newly stated policy of causing needless Response by Applicants to a complete action on the merits before applying a restriction election requirement, then the requirement by the current Examiner must be deemed arbitrary and capricious.

The Alleged Groups

Claims 1-4, 9, 13-16, and 18-21 are pending. The Action alleges that the following three Groups are related as subcombinations and are distinct from each other:

- I. Claims 1-4, 9, 13-14.
- II. Claims 15-16 and 18.
- III. Claims 19-21.

The Office has not shown the alleged Groups I , II, III to be distinct

The burden is on the Examiner to provide valid examples. If Applicants prove or provide an argument that the Examiner's suggested other use cannot be accomplished or is unreasonable, then the burden is on the Examiner to document a viable alternative use or withdraw the requirement. MPEP 806.05 (d). Applicants respectfully submit that the Office has not met its required burden. Each separate utility alleged by the Office is unreasonable, as discussed herein.

The Action also has not provided the required showing of distinct subcombinations. The Action has not provided a showing that the alleged subcombinations do not overlap in scope, are not obvious variants, and are separately usable. For example, the Office has not shown that each alleged subcombination has separate utility. The Office misinterprets and misapplies the meaning of "separately usable."

The alleged Group I

The alleged subcombination I is directed to a method. The alleged separate utility (depots and storage locations) is unreasonable because it is not a method but rather an apparatus. The Office's reliance on an apparatus for separate utility of a method is unreasonable and legally improper.

Furthermore, the Action also has not shown that the alleged subcombinations II and III cannot be used with "medication depots and other smart storage location on a real-time basis" (i.e., the provided separate utility of alleged subcombination I). That is, the Action has not shown that the alleged subcombinations II and III are prevented from being used with "medication depots and other smart storage locations on a real-time basis." Thus, the Office has not shown alleged subcombinations II and III to be distinct from alleged subcombination I.

Additionally, the Office has not explained how "taking a first type of medical item from first location" (the alleged subcombination I) is distinct from the "removing a quantity of the first type of medical item from at least one location" of alleged subcombination II (e.g., claim 15 at step g) or the "quantity of a first type of medical item from" of alleged subcombination III (e.g., claim 19 at step a).

The alleged Group II

The Action also has not shown that alleged subcombinations I and III are prevented from being used in the utility of "controlling the ordering, dispensing, and administration of medical items" (i.e., the provided separate utility of alleged subcombination II). Thus, the Office has not shown the alleged subcombinations I and III to be distinct from alleged subcombination II.

The alleged Group III

The alleged subcombination III is directed to a method. The alleged separate utility (a location) is unreasonable because it is not a method but rather an apparatus. The Office's reliance on an apparatus for separate utility of a method is unreasonable and legally improper.

Additionally, the Action also has not shown that the alleged subcombinations I and II are prevented from being used with "an intensive care treatment location" (i.e., the provided separate utility of alleged subcombination III). Thus, the Office has not shown the alleged subcombinations I and II to be distinct from the alleged subcombination III.

The issue of Rejoinder of claims has not been considered

The Action also has not addressed the issue of rejoinder of claims (MPEP § 821.04). Applicants respectfully submit that even if the Office were to somehow show (which it hasn't) restrictable claims as alleged, that process claims would be entitled to rejoinder. Applicants reserve all rights to rejoinder.

The Restriction Requirement Is Without Legal Basis

Applicants also respectfully wish to point out that the Action fails to state a legally sufficient basis for imposing a restriction requirement. The Action indicates that the restriction requirement is solely based on a showing of the alleged inventions being “distinct.” The statutory authority for the Patent Office to impose a restriction requirement is found in 35 U.S.C. § 121. The statute expressly states that before the Patent Office may require restriction, the inventions must be both “independent” and “distinct.” The regulations that have been promulgated pursuant to this statute, 37 C.F.R. § 1.141 and 37 C.F.R. § 1.142, both expressly state that before a restriction requirement may be imposed the inventions claimed must be both independent and distinct.


In the Action, there are only unsupported assertions that the sets of claims are “distinct.” There are no assertions that the sets of claims are “independent,” as is required. This standard does not comply with the statutory requirements. Therefore, the standard used in the Action for seeking to impose a restriction requirement is legally incorrect due to noncompliance with the clear wording of both the statute and the regulations promulgated thereunder. The application of such an incorrect legal standard is arbitrary, capricious, and contrary to law in violation of the Administrative Procedures Act.

Furthermore the Patent Office has acknowledged that before claimed inventions can be considered to be "independent" the inventions must be unconnected in design, operation, or effect. MPEP § 802.01. The Office has not shown that the claims directed to Applicants' invention are unrelated in design, operation, and effect. Thus, the statutory requirements are not met and no restriction requirement may be imposed.

Conclusion

For all the foregoing reasons it is respectfully submitted that there is no valid basis for the restriction election requirement. Applicants respectfully request that their Petition be granted and the requirement be withdrawn. If further request for reconsideration is required, then this Petition should be considered as such.

Respectfully submitted,



Ralph E. Jocke Reg. No. 31,029
WALKER & JOCKE
231 South Broadway
Medina, Ohio 44256
(330) 721-0000